



021-28-04

1636

In the Application of:

Sharma et al.

Serial No.: 10/043,774

Filing Date: January 10, 2002

**For: Human Hematopoietic Growth
Regulatory Gene and Uses**

Examiner:

Group Art Unit: 1636

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1. We are transmitting herewith the attached papers for the above-identified patent application:

- ☒ Information Disclosure Statement
- ☒ PTO Form 1449 and cited references

2. **GENERAL AUTHORIZATION TO CHARGE OR CREDIT FEES:** Please charge any additional fees or credit overpayment to Deposit Account No. **13-2490**.
3. **CERTIFICATE OF MAILING UNDER 37 CFR § 1.8:** The undersigned hereby certifies that this Transmittal Letter and the papers, as described in paragraph 1 herein-above, are being deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, Alexandria VA 22313-1450 on this **26th** day of **April, 2004**.

By:

Kevin E. Noonan
Registration No. 35,303



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 02-013)

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Sharma et al.

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Copies of the references cited below are enclosed. These references are also listed on the enclosed PTO Form 1449.

In the judgment of the undersigned, portions of the listed references may be material to the Examiner's consideration of the presently pending claims. This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

Applicants do not believe any fee is due with this submission. If this belief be in error and the Patent Office determines that the fee prescribed in the relevant portion of 37 C.F.R. Section 1.97 is applicable, the undersigned representative by his signature hereby authorizes any such fee to be debited from Deposit Account 13-2490.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff

Date: April 26, 2004

Kevin E. Noonan
Reg. No. 35,303

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application No.	10/043,774
Filing Date:	January 10, 2002
First Named Inventor	Sharma et al.
Group Art Unit	1636
Examiner Name	McKelvey
Attorney Docket No.	02-013

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Figures Appear
		Number	Kind Code ² (if known)			
	1	4,683,195		Mullis et al.,	07-28-1987	
	2	4,683,202		Mullis et al.	7-28-1987	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	3	WO	00/32039	A1	Duke University	06-08-2000		

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English translation is attached.

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Substitute for form 1449A/PTO

Complete if Known

Application No.

10/043,774

Filing Date:

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First Named Inventor

Sharma et al.

Group Art Unit

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Examiner Name

McKelvey

Attorney Docket No.

02-013

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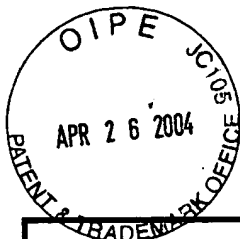
OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	4	Morrison et al., "The Biology of Hematopoietic Stem Cells" Annu. Rev. Cell Dev. Biol. 11:35-71 (1995).	
	5	Chen et al., "Delineation of the human hematolymphoid system: potential applications of defined cell populations in cellular thereapy" Immunological Reviews 157:41-51 (1997).	
	6	Goodell et al. "CD34+ or DC34-: Does it Really Matter?" Blood 94:2545-47 (1999).	
	7	Huang et al., "Symmetry of Initial Cell Divisions Among Primitive Hematopoietic Progenitors is Independent of Ontogenic Age and Regulatory Molecules" Blood 94:2595-2604 (1999).	
	8	Vaziri et al. "Evidence for a mitotic clock in human hematopoietic stem cells: Loss of telomeric DNA with age" Proc. Natl. Acad. Sci. 91:9857-60 (1994).	
	9	Lansdorp et al., "Developmental changes in the function of hematopoietic stem cells" Experimental Hematology 23:187-191 (1995).	
	10	Van der Loo et al., "Marrow- and Spleen-Seeding Efficiencies of All Murine Hematopoietic Stem Cell Subsets Are Decreased by Preincubation with Hematopoietic Growth Factors" Blood 85:2598-2606 (1995).	
	11	Peters et al., "Murine Marrow Cells expanded in culture with IL-3, IL-6, IL-11, and SCF acquire an engraftment defect in normal hosts" Experimental Hematology 23:461-469 (1995).	
	12	Peters et al., "Ex Vivo Expansion of Murine Marrow Cells with Interleukin-3 (IL-3), IL-6, IL-11, and Stem Cell Factor Leads to Impaired Engraftment in Irradiated Hosts", Blood 87:30-37 (1996).	
	13	Yonemura et al., "Interleukin 3 or interleukin 1 abrogates the reconstituting ability of hematopoietic stem cells" Proc. Natl. Acad. Sci. 93:4040-44 (April 1996).	
	14	Sharma et al., "Human CD34+ stem cells express the hiwi gene, a human homologue of the Drosophila gene piwi" Blood 97:426-434 (2001).	
	15	Hoffman et al., "Progress in the development of systems for in vitro expansion of human hematopoietic stem cells" Current Opinion in hematology 184-191 (1999).	
	16	Zon et al., "Developmental Biology of Hematopoiesis" Blood 86:2876-2891 (1995).	
	17	Lewis "A gene complex controlling segmentation in Drosophila" Nature 276:565-70 (1978).	
	18	Tabara et al., "The rde-1 Gene, RNA Interference, and Transposon Silencing in C elegans" Cell 99:123-32 (1999).	

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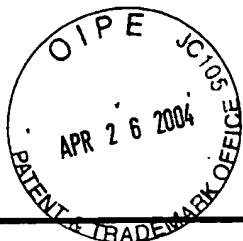
Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application No.	10/043,774
				Filing Date:	January 10, 2002
				First Named Inventor	Sharma et al.
				Group Art Unit	1636
				Examiner Name	McKelvey
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	19	Sidow et al., "Diversification of the Wnt gene family on the ancestral lineage of vertebrates" Proc. Natl. Acad. Sci. 89:5098-5102 (1992).		
	20	Austin et al., "A Role for the Wnt Gene Family in Hematopoiesis: Expansion of Multilineage Progenitor Cells" Blood 89:3624-3635 (1997).		
	21	Nusslein-Volhard et al., "Mutations affecting segment number and polarity in Drosophila" Nature 287:795-801(1980).		
	22	Lin et al., "Germline Stem cell Division and Egg Chamber Development in Transplanted Drosophila Germaria" Developmental Biology 159:140-152 (1993).		
	23	Lin et al., "A Novel group of pumilio mutations affects the asymmetric division of germline stem cells in the Drosophila ovary" Development 124:2463-76 (1997).		
	24	Lin et al., "The self-renewing mechanism of stem cells in the germline" Curr Opin Cell Biol. 687-693 (1993).		
	25	Cox et al., "A Novel class of evolutionarily conserved genes defined by piwi are essential for stem cell self-renewal" Genes & development 12:3715-3727 (1998).		
	26	Lin et al., "The tao of stem cells in the germline" Ann. Rev. of Genet. 455-491 (1999).		
	27	Benfey et al., "Stem cells: A tale of two kingdoms" Curr. Biol. 9:171-172 (1999).		
	28	King et al., "Somatic signaling mediated by fs(1)Yb is essential for germline stem cell maintenance during drosophila oogenesis" Development 126:1833-44 (1999).		
	29	Labow et al., "Conversion of the lac Repressor into an Allosterically Regulated Transcriptional Activator for Mammalian Cells" Mol. Cell. Biol. 10:3343-56 (1990).		
	30	Thomas and Capecchi, "Site-Directed Mutagenesis by Gene Targeting in Mouse Embryo-Derived Stem Cells" Cell 51:503-512 (1987).		
	31	Bertling et al., "Transfection of a DNA/Protein Complex into Nuclei of Mammalian Cells Using Polyoma Capsids and Electroporation" Bioscience Reports 7:107-112 (1987).		
Examiner Signature			Date Considered	

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				Group Art Unit	1636
				Examiner Name	McKelvey
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	32	Smithies et al., "Insertion of DNA sequences into the human chromosomal β -globin locus by homologous recombination" Nature 317:230-234 (1985).		
	33	Ando et al. "Regulation of G1/S transition by cyclins D2 and D3 in hematopoietic cells" Proc. Natl. Acad. Sci 90:9571-75 (1993).		
	34	Abkowitz et al., "Evidence that hematopoiesis may be a stochastic process in vivo" Nature Medicine 2:190-197 (1996).		
	35	Uchida et al. "Primitive Human Hematopoietic Cells Displaying Differential Efflux of the Rhodamine 123 Dye Have Distinct Biological Activities" Blood 88:1297-1305 (1996).		
	36	Morrison et al., "Cyclophosphamide/granulocyte colony-stimulating factor induces hematopoietic stem cells to proliferate prior to mobilization" Proc. Natl. Acad. Sci. 94:1908-1913 (1997).		
	37	Cheshier et al., "In vivo proliferation and cell cycle kinetics of long-term self-renewing hematopoietic stem cells" Proc. Natl. Acad. Sci. 96:3120-25 (1999).		
	38	Akazawa et al., "Molecular Characterization of a Rat Negative Regulator with a Basic Helix-Loop-Helix Structure Predominantly Expressed in the Developing Nervous System" Journ of Biol. Chemistry 267:21879-85 (1992).		
	39	Bradford et al., "Quiescence cycling, and turnover in the primitive hematopoietic stem cell compartment" Exp. Hematol. 25:445-453 (1997).		
	40	Postigo et al., "ZEB, a vertebrae homolog of Drosophila Zfh-1, is a negative regulator of muscle differentiation" 16:3935-43 (1997).		
	41	Cox et al., "piwi encodes a nucleoplasmic factor whose activity modulates the number and division rate of germline stem cells" Development 503-514 (2000).		
	42	Cox et al., "A novel class of evolutionarily conserved genes defined by piwi are essential for stem cell self-renewal" Genes & Develop. 12:3715-27 (1998).		

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	43	Davis et al., "Porcine Brain Microvascular Endothelial Cells Support the In Vitro Expansion of Human Primitive Hematopoietic Bone Marrow Progenitor Cells with a High Relating Potential: Requirement for Cell-to-Cell Interactions and Colony-Stimulating Factors" Blood 85:1751-61 (1995).		
	44	Terstappen et al., "Sequential Generations of Hematopoietic Colonies Derived From Single Nonlineage-Committed CD34+CD38- Progenitor Cells" Blood 77:1218-1227 (1991).		
	45	Bazil et al., "Apoptosis of Human Hematopoietic Progenitor Cells Induced by Crosslinking of Surface CD43, the Major Sialoglycoprotein of Leukocytes" Blood 86:502-511 (1995).		
	46	Gluzman et al., "SV40-Transformed Simian Cells Support the Replication of Early SV40 Mutants" Cell 23:175-182 (1981).		
	47	Pittenger et al., "Multilineage Potential of Adult Human Mesenchymal Stem Cells" Science 284:143-147 (1999).		
	48	Dexter et al., "Conditions Controlling the Proliferation of Haemopoietic Stems Cells in Vitro" J. Cell. Physiol. 91:335-344 (1977).		
	49	Wineman et al. "Functional Heterogeneity of the Hematopoietic Microenvironment: Rare Stromal Elements Maintain Long-term Repopulating Stem Cells" Blood 87:4082-90 (1996).		
	50	Chenchik et al., "Full-Length cDNA Cloning and Determination of mRNA 5' and 3' Ends by Amplification of Adaptor-Ligated cDNA" Biotechniques 21:526-534 (1996).		

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